

UNITED STATES DISTRICT COURT FOR THE
DISTRICT OF DELAWARE

ABBOTT LABORATORIES, an Illinois
corporation,

Plaintiff,

v.

BANNER PHARMACAPS INC., a Delaware
corporation,

Defendant.

Civil Action No. 07-CV-00754-GMS

**BRIEF IN SUPPORT OF ABBOTT LABORATORIES' MOTION TO DISMISS
BANNER'S UNFAIR COMPETITION COUNTERCLAIM**

February 20, 2008

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I. NATURE AND STAGE OF PROCEEDINGS

On November 21, 2007, Abbott Laboratories (“Abbott”) filed a complaint against Banner Pharmacaps Inc. (“Banner”), alleging that Banner’s submission of New Drug Application No. 22-152 (“Banner’s NDA”), which seeks FDA approval to market a proposed generic version of Abbott’s Depakote® (divalproex sodium), constitutes infringement of two patents owned by Abbott: U.S. Patent Nos. 4,988,731 and 5,212,326 (collectively, the “Patents”). (*See generally* Complaint (D.I. 1).) In its complaint, Abbott asks this Court to (i) find that the product described in Banner’s NDA would, if allowed on the market, infringe Abbott’s Patents, (ii) enjoin Banner from manufacturing, selling, offering to sell, importing, or using the product described in its NDA during the life of the Patents; and (iii) order that Banner’s NDA cannot be approved prior to the Patents’ expiration. (*Id.* at 6.) On January 28, 2008, Banner answered and asserted two counterclaims – one seeking a declaratory judgment of non-infringement (which Abbott has answered) and one for “unfair competition,” which Abbott now moves to dismiss. (*See generally* Answer & Counterclaims (D.I. 7).)

No schedule has yet been set in this case, which was newly reassigned to this Court. (*See* Order Reassigning Case (D.I. 8).)

II. SUMMARY OF THE ARGUMENT

To allege an unfair-competition claim, Banner must claim that (1) it had a reasonable expectancy of entering a valid business relationship; (2) Abbott wrongfully interfered with that relationship; and (3) its legitimate expectancy was defeated by Abbott’s interference, thereby causing it harm. Banner has not done so, and its scant, four-paragraph counterclaim must therefore be dismissed. Moreover, because the action alleged as the basis of Banner’s counterclaim (Abbott’s filing of this complaint) was expressly permitted by statute, Banner could never properly state an unfair competition claim. Since Banner cannot overcome this fatal

deficiency by repleading, its second counterclaim should be dismissed with prejudice, for the following reasons.

First, Banner alleges no expectancy of a valid business relationship.

Second, in conclusory fashion, Banner asserts that Abbott's conduct was "wrongful and anticompetitive[.]" (Counterclaim (D.I. 7) ¶ 18.) This conclusory allegation is insufficient to state a claim for unfair competition. Even setting aside this pleading defect, Banner's counterclaim suffers from a more serious flaw: as a matter of law, actions expressly authorized by statute are *not* "wrongful interference" and cannot be the basis for an unfair competition claim. Here, because Abbott's conduct in filing this lawsuit was authorized by statute, Banner's counterclaim is without merit.

Third, Banner's claim that it will suffer "economic harm" is similarly deficient. Again, this unsupported, imprecise conclusion is insufficient to state a claim. And, as a matter of law, Banner's claimed harm (based on an alleged competitive disadvantage that flows naturally from a statutory scheme) is not a legally cognizable injury that may be remedied by an unfair competition claim.

In sum, because Banner fails adequately to plead any of the required elements – and, more importantly, because its allegations as to at least two of those elements fail as a matter of law – its claim for unfair competition should be dismissed, with prejudice.

III. STATEMENT OF FACTS

A. The Hatch-Waxman Act and the Filing of a § 505(b)(2) New Drug Application

The FDA maintains a list of all pharmaceutical drugs approved for sale in the United States. This list – formally titled "Approved Drug Products With Therapeutic Equivalence Indications" – is commonly referred to as the "Orange Book." See <http://www.fda.gov/cder/ob/>.

The Orange Book contains a variety of information about approved drug products, including the trade name, active ingredient, date of approval, and available dosage forms and strengths. It also lists each patent that the innovator contends covers some aspect of the drug product. The Orange Book entry for Abbott's Depakote® product, for instance, lists the Patents, which cover the active ingredient in Depakote®, divalproex sodium.

Under the Hatch-Waxman Act, a manufacturer seeking FDA approval of a drug product can choose one of three options: (i) a New Drug Application ("NDA") under § 505(b)(1) of the Act, which requires the applicant to provide detailed information regarding the proposed drug's safety and efficacy, including data from very costly clinical studies; (ii) a NDA under § 505(b)(2) of the Act, which permits the applicant to rely on safety and efficacy data previously gathered by an innovator with respect to an approved drug product (thus avoiding conducting costly clinical studies of its own), even though the § 505(b)(2) applicant contends that its proposed generic product is somehow different from the innovator product; or (iii) an Abbreviated New Drug Application ("ANDA"), which relies directly on an innovator's clinical data and requires the applicant to certify that the active pharmaceutical ingredient in its proposed generic drug is identical to that of a previously-approved innovator drug. *See* 21 U.S.C. § 355(b),(j). Here, Banner has filed a New Drug Application under § 505(b)(2) of the Act.

Like an ANDA, a § 505(b)(2) NDA relies on safety and efficacy studies performed by an innovator company (like Abbott) on a previously approved product, referred to as the reference-listed drug. *See id.* The Hatch-Waxman Act requires a § 505(b)(2) applicant (just like an ANDA applicant) to address patents listed in the Orange Book for the reference-listed drug on which the applicant relies for clinical data as part of the application process. And, like an ANDA applicant, a § 505(b)(2) applicant must submit one of four certifications regarding any patents

listed by the innovator in the FDA's Orange Book in conjunction with the reference-listed drug. *See* 21 U.S.C. § 355(b)(2)(A)(i)-(iv). These four certifications are: (i) the innovator has not listed any patent information with FDA; (ii) any listed patent has expired; (iii) the listed patent expires on a date before which the § 505(b)(2) applicant is seeking to market its product; or (iv) the listed patent is invalid or will not be infringed by the manufacture, use, or sale of the drug described in the NDA. *Id.*¹ An applicant that includes a "Paragraph IV certification" in its § 505(b)(2) NDA is required to transmit notice of this certification to the patent holder, along with a detailed explanation of the legal and factual bases for the certification. *See* 21 U.S.C. § 355(b)(3). This notice is to contain an offer allowing the patent holder confidential access to all or part of the NDA for purposes of evaluating a potential infringement action. *See* 21 U.S.C. § 355(c)(3)(D)(i)(III).

The Hatch-Waxman Act provides that, if the patent holder files an infringement action against the § 505(b)(2) applicant within 45 days of receiving such a notice, then a statutory stay automatically is triggered – barring the FDA from approving the NDA for 30 months and affording the parties time to resolve the infringement litigation before the proposed generic product is marketed to the public. *See* 21 U.S.C. § 355(c)(3)(C).

B. Abbott's Depakote® and Its Orange-Book-Listed Patents

Abbott owns the Patents, both of which cover divalproex sodium, the active ingredient in Abbott's widely-used anti-convulsive drug Depakote®. (*See* Compl. (D.I. 1) Ex. A & B.) The Patents have been unanimously upheld as valid and enforceable by the Northern District of Illinois and the Federal Circuit. *See Abbott Labs. v. TorPharm, Inc.*, 156 F.Supp.2d 738, 747-

¹ The certifications made by generic applicants are commonly referred to in shorthand by their paragraph numbers. For example, a certification claiming that the innovator's listed patent is invalid or would not be infringed by the proposed generic product is referred to as a "Paragraph IV certification."

749 (N.D. Ill. 2001); *Abbott Labs. v. TorPharm, Inc.*, 300 F.3d 1367, 1378-80 (Fed. Cir. 2002); *see also Abbott Labs. v. Alra Labs.*, 1997 WL 667796, at *8-10 (N.D. Ill. 1997).

The FDA approved Abbott's New Drug Application No. 18-723 to market Depakote® on March 10, 1983. (Compl. (D.I. 1) ¶ 7.) As a result, Depakote® is listed in the Orange Book. (*Id.*) The Patents are listed in the Orange Book in association with Depakote®. (*Id.* ¶ 12.)

C. Banner's Paragraph IV Notice

Abbott received a letter from Banner, dated October 9, 2007, which stated that Banner had submitted NDA No. 22-152 under § 505(b)(2), requesting approval to market a purported generic version of Depakote® in 125, 250, and 500 mg dosage strengths. (*Id.* ¶ 13.) The letter included a Paragraph IV certification, asserting that the Banner product would not infringe the Patents, and a declaration that Banner sought FDA approval to market its product before the Patents expired. (*Id.*) In its letter, Banner claimed that the active ingredient in its product is valproic acid, but Banner did not select one of the many FDA-approved valproic acid products as the reference listed drug for its NDA. Instead, Banner averred to FDA that the appropriate reference listed drug for its product is Abbott's Depakote®, which has the patented divalproex sodium as its active ingredient, not valproic acid.

Banner's notice purported to offer Abbott access to the NDA so that Abbott could evaluate in advance whether to bring suit. The notice stated that the NDA would be provided to Abbott's outside counsel and their staff, up to 5 in-house Abbott attorneys, and independent consultants or experts retained by Abbott. Shortly after receiving the notice, Abbott contacted Banner to secure the NDA for review by its inside and outside counsel and consultants. Despite the promised offer of access, however, Banner refused to provide any portion of the NDA to Abbott or its consultants – insisting that the most Abbott could do was to view one portion of the NDA at Banner's headquarters in North Carolina. No product samples were offered for testing.

Banner would not budge on this issue, effectively denying Abbott's counsel and consultants any reasonable access to the NDA or the product.

D. Abbott Files Suit Against Banner

Within 45 days of receiving Banner's notice, Abbott filed its complaint. (*See generally* Compl. (D.I. 1).) By operation of statute, Abbott's filing triggered a 30-month stay of FDA approval of Banner's NDA. *See* 21 C.F.R. § 314.107(b)(3)(i)(A).

IV. ARGUMENT

In deciding a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), the court must "assume the truth of all well pleaded factual allegations in the complaint and must construe them in the light most favorable to the non-moving party." *Digene Corp. v. Ventana Med. Sys., Inc.*, 511 F.Supp.2d 407, 410 (D. Del. 2007). However, the Court "will not accept unsupported conclusions, unwarranted inferences, or sweeping legal conclusions cast in the form of factual allegation." *Id.* (internal quotations omitted). Dismissal is warranted where "no relief could be granted under any set of facts consistent with the allegations of the complaint." *Morse v. Lower Merion Sch. Dist.*, 132 F.3d 902, 906 (3d Cir. 1997).

To allege an unfair-competition claim, Banner must claim that (1) it had a "reasonable expectancy of entering a valid business relationship"; (2) Abbott "wrongly interfere[d]" with that relationship; and (3) Abbott's interference "defeat[ed] [Banner's] legitimate expectancy and cause[d] [Banner] harm." *Total Care Physicians, P.A. v. O'Hara*, 798 A.2d 1043, 1057 (Del. Super. Ct. 2001). Here, Banner claims only that Abbott filed "this action without substantial justification for the wrongful and anticompetitive purpose of invoking the 30-month statutory delay . . . in order to prevent the FDA from issuing final approval to Banner's NDA 22-152." (Counterclaim (D.I. 7) ¶ 18.) As a matter of law, this is insufficient to state a claim upon which relief may be granted. Indeed, Banner's counterclaim fails to allege the predicate facts for all

three elements of a claim of unfair competition; as such, its counterclaim should be dismissed. And, because the facts underlying Banner's counterclaim could *never* give rise to a viable claim against Abbott, dismissal should be with prejudice.

A. Banner Fails To Allege That It Had a Reasonable Expectancy of Entering Into a Valid Business Relationship.

Banner's counterclaim is devoid of any allegation that it had a reasonable expectancy of entering into a business relationship with any third party. Instead, Banner merely alleges that Abbott's filing of this suit prohibited immediate FDA approval of its generic drug. (*Id.*) This is not enough to plead the first element of a claim of unfair competition.

A claim for unfair competition requires specific evidence of a legitimate expectancy of a business relationship. *See Am. Homepatient, Inc. v. Collier*, 2006 WL 1134170, at *4 (Del. Ch. April 19, 2006) (general evidence regarding past business dealings was insufficient). It is unclear from Banner's bare-bones allegations whether the business relationship that supposedly has been thwarted is between Banner and a prospective customer for its unapproved generic drug, or with the FDA itself. Either way, the claim fails.

If the alleged business relationship is with a hypothetical customer, the very nature of the pharmaceutical industry precludes the "reasonable expectancy" of a relationship necessary to sustain an unfair-competition claim. Where an industry enjoys "robust competition," a legitimate expectancy of a valid business relationship "might be a bit unreasonable without a written contract[.]" *Id.* (noting that the home respiratory and medical equipment services industry is particularly competitive). Given the pharmaceutical industry's competitive nature, Banner's lack of specific details supporting the existence of any legitimate business expectancy is fatal to its claim. *Cf. Merck & Co. v. Apotex, Inc.*, 488 F. Supp. 2d 418, 428 (D. Del. 2007) (Sleet, J.) (noting that the pharmaceutical industry is "fiercely competitive").

And, to the extent that Banner attempts to make its interactions with the FDA the “legitimate expectancy of a business relationship” required to state an unfair-competition claim, this effort, too, must fail. FDA approval of a NDA is not mandatory, but is conditioned on numerous statutory provisions regarding safety, efficacy, patent rights, and other factors. *See generally* 21 U.S.C. § 355; *see also* *Merck*, 488 F. Supp. 2d at 428 (there is “no absolute right of a generic drug company to enter the market in which a pioneer drug company . . . ha[s] legally achieved some market exclusivity”). Moreover, no reported decision has ever suggested that the “business relationship” required as part of the tort of unfair competition is so broad as to include a *governmental agency* acting in its appointed regulatory role. For this reason, too, Banner’s claim is flawed.

B. Banner Fails Adequately To Allege – and, Indeed, Cannot Allege – That Abbott’s Statutorily Authorized Actions Were “Wrongful.”

For its allegation that Abbott “wrongly interfered” with this unsupported business relationship, Banner offers only two conclusory assertions: (i) Abbott lacked a “bona fide, objectively reasonable and good faith basis to allege infringement”; and (ii) Abbott filed suit “without substantial justification” and for “wrongful and anticompetitive purpose[s.]” (Counterclaim (D.I. 7) ¶¶ 17, 18.)

First, neither of these two statements are well-pleaded factual allegations. To the contrary, they are “unsupported conclusions” that this Court need not credit. *See Digene*, 511 F.Supp.2d at 410 (the Court “will not accept unsupported conclusions . . . cast in the form of factual allegation” on a motion to dismiss).

Second, Banner knows both of these statements to be false. Abbott *had* a good-faith basis to file suit because Banner’s filing of its NDA under 21 U.S.C. § 355(b)(2) (§ 505(b)(2) of the Act) – with a request that the FDA approve Banner’s product prior to the expiration of the

Patents – is, by itself, an act of infringement that provided sufficient basis for Abbott to file this suit. *See* 35 U.S.C. § 271(e)(2); *see also Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1342 (Fed. Cir. 2007) (“The very act of submitting an ANDA [with a Paragraph IV certification] is an act of infringement.”). As this Court has recognized, Abbott had no obligation to review the NDA or test product samples before filing suit (and had no reasonable opportunity to do so in any event, given Banner’s conditions), because Banner’s submission of the NDA is, by itself, enough to justify this action. *See Merck*, 488 F. Supp. at 429 (Merck sued Apotex based solely on receipt of Apotex’s Paragraph IV certification letter, without first reviewing the ANDA; the Court noted that Apotex’s filing of an ANDA with a Paragraph IV certification was, by statute, an act of infringement, and “[t]he statutory provisions that allow suit under these circumstances render the patentee’s subjective motivations for filing suit irrelevant”).²

As such, Abbott’s conduct – the filing of a complaint based upon the filing of an application containing a Paragraph IV certification – is not a “wrongful” act. The Hatch-Waxman Act unequivocally instructs that the filing of Banner’s NDA is an act of infringement (*id.*), and, as the holder of a valid patent, Abbott has the right to sue to enforce that patent. *See* U.S. CONST., art. I, § 8. An unfair-competition claim cannot stand when the conduct of the party accused of unfair competition is expressly authorized. *See Collier*, 2006 WL 1134170, at *4

² Although Banner’s Paragraph IV certification alleges that its product is valproic acid, Banner was unwilling to provide Abbott with its NDA in full to confirm these allegations prior to Abbott filing the lawsuit. Abbott cannot be deemed to have engaged in unfair competition when it was not provided with support for Banner’s allegations. Banner may claim that its product is valproic acid, but Banner may be infringing Abbott’s Patents at any point in the manufacturing process. Without affording Abbott full review of the NDA, Banner cannot be heard to complain that Abbott’s filing of the instant action is in any way unfair. Indeed, Banner could have avoided having to address Abbott’s Patents at all by performing its own clinical studies for its own product. It chose, instead, to rely on Abbott’s clinical studies.

(where defendant's actions were "expressly permitted" by a settlement agreement to which plaintiff was a party, there was no "wrongful" act for an unfair-competition claim).

Accordingly, not only has Banner failed to plead the second element of an unfair-competition claim, it *cannot* allege that Abbott's statutorily authorized actions are the basis of such a claim. No amount of artful pleading can paper over this fatal flaw in Banner's claims.

C. Banner Fails To Allege – and Cannot Allege – That It Has Suffered any Identifiable Harm.

For the third prong, Banner claims (quite generally) that it has suffered "economic harm" by Abbott's filing this lawsuit. (*See* Counterclaim (D.I. 7) ¶ 18.) Again, this non-specific allegation of harm is nothing more than a bald assertion, devoid of any factual support, and this Court ought not credit it. *See Digene*, 511 F.Supp.2d at 410. For example, Banner has not alleged that it is prepared to market or sell its generic product. Without at least this much, Banner has failed to allege cognizable injury, and its unfair competition counterclaims must be dismissed.

Even if Banner could allege that it was prepared to market its product (which it apparently cannot do), Banner cannot, as a matter of law, claim that it has suffered a legally cognizable injury as a result of Abbott's actions. The injuries Banner complains of are the application of the statutory 30-month stay and a 6-month period of regulatory exclusivity to Banner's NDA. (*See* Counterclaim (D.I. 7) ¶ 18.) Neither action was caused by Abbott, however. As discussed above, the 30-month stay of FDA approval of the NDA was triggered automatically under the Hatch-Waxman Act by the filing of Abbott's complaint (which, as discussed above, was fully authorized by the statute). *See* 21 C.F.R. § 314.107(b)(3)(i)(A). Similarly, the six-month period of pediatric exclusivity that Banner complains about is also a product of statute. At FDA's request, Abbott undertook pediatric studies to demonstrate the

safety and efficacy of Depakote® in children. In return for successfully completing these studies, Abbott was entitled – again, by statute – to a period of regulatory exclusivity (so-called “pediatric exclusivity”) that prohibits FDA from approving any purported generic versions of Depakote® for six months after the expiry of the Patents (or, until July 29, 2008). *See* 28 U.S.C. § 355a(c)(2)(B).

Furthermore, a claimed competitive disadvantage suffered as a result of a 30-month stay or a period of pediatric exclusivity awarded under the Hatch-Waxman act is not a legally cognizable injury. *See Merck*, 488 F.Supp.2d at 428 (“not every business disadvantage is appropriately deemed legal injury”). As this Court previously explained, there is “no absolute right of a generic drug company to enter the market in which a pioneer drug company . . . ha[s] legally achieved some market exclusivity.” *Id.* Where an alleged injury is simply a ““product of the Hatch-Waxman scheme and the fact that [a company] has acted in a manner permitted under that scheme[,]” this Court has declined to deem the resulting “business disadvantage” a “legal injury.” *Id.* (quoting *Teva Pharms. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1338 (Fed. Cir. 2005)). Thus, Banner’s allegation of harm – even if it were properly pleaded (and it is not) – is insufficient to satisfy the third prong required to state a claim for unfair competition

V. CONCLUSION

For the reasons set forth above, Banner's unfair-competition claim fails as a matter of law, and should be dismissed, with prejudice, under Federal Rule of Civil Procedure 12(b)(6).

Dated: February 20, 2008

Respectfully submitted,

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I hereby certify that, on February 20, 2008, a true and correct copy of the foregoing document entitled **Abbott's Brief in Support of Abbott's Motion to Dismiss Banner's Unfair Competition Counterclaim** was served on the following persons via CM/ECF filing and the following methods:

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